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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,447	02/09/2001	Dipak K. Banerjee	P19850.p06	6690

7055 7590 05/20/2003

GREENBLUM & BERNSTEIN, P.L.C.
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RESTON, VA 20191

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

12

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/779,447

Applicant(s)

BANERJEE ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6 & 7</u> . | 6) <input type="checkbox"/> Other: |

Art Unit: 1623

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Response to Restriction Requirement

Applicants have elected with traverse Group I. Applicant's arguments with regards to the exclusion of Groups II and III is persuasive and an examination on the merits of the claims comprising Groups I-III is set forth below.

However, the restriction of Groups IV-XIV is maintained. Claims 19-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The traversal is on the ground(s) that an undue burden would not be imposed upon the examiner. This is not found persuasive because the distinct classification of Groups IV-XIV warrants maintenance of the restriction and also supports the undue burden that would be imposed upon the examiner of record.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Presta et al., *Cancer Research* vol. 59, pp. 2417-24.

Claim 1 is drawn to a method for inhibiting angiogenesis comprising administering a nucleoside.

Presta anticipates the claim as it teaches a method for inhibiting angiogenesis via administration of the nucleoside 6-Methylmercaptapurine riboside.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Banerjee et al., *Indian J. of Biochem. and Biophysics*, vol. 30(6), pp. 389-94.

Banerjee anticipates claims 1-5 as it teaches that the angiogenic process of capillary endothelial cell proliferation is linked to the synthesis of N-linked oligosaccharide chains which is inhibited by the pyrimidine nucleoside tunicamycin (which contains a linked glucosamine).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

Art Unit: 1623

at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Banerjee et al., *Indian J. of Biochem. and Biophysics*, vol. 30(6), pp. 389-94.

Claims 1-14 and 16-18 is drawn to a method for inhibiting angiogenesis comprising administering a pyrimidine nucleoside, wherein the nucleoside comprises N-acetylated glucosamine or comprises tunicamycin and functional derivatives thereof.

Claim 15 is drawn to the method of claim 1, wherein the inhibition of angiogenesis occurs in a variety of diseases wherein inhibition of angiogenesis would be beneficial, i.e. diabetic retinopathy, atherosclerotic plaques, scleroderma, etc.

Banerjee teaches the use of a pyrimidine nucleoside as an antiangiogenic agent as it teaches that the angiogenic process of capillary endothelial cell proliferation is linked to the synthesis of N-linked oligosaccharide chains which is inhibited by the pyrimidine nucleoside tunicamycin (which contains a linked glucosamine).

Banerjee does not specifically mention the claimed homologs of tunicamycin nor the various diseases wherein angiogenesis may be present; however, characteristics normally possessed by members of a homologous series are principally the same, chemists would in general know what to expect in adjacent members of homologs of a known compound. The test of patentability of a compound that is a homologue of a prior art compound is whether the claimed compound possesses beneficial characteristics which are unexpected and unobvious. One of skill in the art would have a reasonable expectation of success in the use of homologs of tunicamycin as angiogenic compounds given the efficacy of the parent compound. There is no data in the prior art nor the specification that presents some property of these homologs apart from that of the parent compound, chiefly the inhibition of angiogenesis. One of skill in the art would also have a reasonable expectation of success that a compound which inhibits

Art Unit: 1623

angiogenesis would be beneficial in various disease states which may be disrupted by or thrive on the process of angiogenesis. Applicant's claims regarding the administration timetable of the known compound is not patentable given that one of skill in the art practicing the administration of any medicinal compound determines the optimum dosage for each patient, based on a variety of physical and metabolic factors.

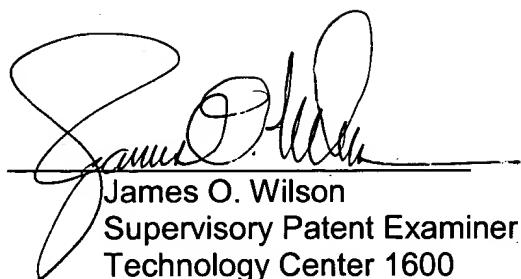
It would have been *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a pyrimidine nucleoside such as tunicamycin to inhibit angiogenesis.

A person of ordinary skill in the art would have been motivated to use a pyrimidine nucleoside such as tunicamycin given the prior art's recognition of tunicamycin as an inhibitor of the pathway leading to the angiogenic process of capillary endothelial cell proliferation.

Art Unit: 1623

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.